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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	Case No. CR-18-00258-EJD
)	
Plaintiff,)	MS. HOLMES' MOTION TO EXCLUDE
)	EXPERT TESTIMONY OR, IN THE
v.)	ALTERNATIVE, COMPEL ADEQUATE RULE
)	16 DISCLOSURE
ELIZABETH HOLMES and)	
RAMESH "SUNNY" BALWANI,)	Date: July 20, 2020
)	Time: 1:30 p.m.
Defendants.)	CTRM: 4, 5th Floor
)	
)	Hon. Edward J. Davila
)	
)	

MOTION TO EXCLUDE EXPERT TESTIMONY
OR IN THE ALTERNATIVE COMPEL ADEQUATE RULE 16 DISCLOSURE
CR-18-00258 EJD

NOTICE OF MOTION

PLEASE TAKE NOTICE that on July 20, 2020, at 1:30 p.m., or on such other date and time as the Court may order, in Courtroom 4 of the above-captioned Court, 280 South 1st Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Elizabeth Holmes will and hereby does respectfully move the Court pursuant to Rule 16 of the Federal Rules of Criminal Procedure for an order excluding the testimony of certain of the government's disclosed experts, or in the alternative, compelling the government to provide an adequate Rule 16 disclosure by August 11, 2020. The Motion is based on the below Memorandum of Points and Authorities and Exhibits, the Declaration of Amy Mason Saharia, the record in this case, and any other matters that the Court deems appropriate.

DATED: July 2, 2020

/s/ Amy Mason Saharia
KEVIN DOWNEY
LANCE WADE
AMY MASON SAHARIA
KATHERINE TREFZ
Attorneys for Elizabeth Holmes

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MEMORANDUM OF POINTS AND AUTHORITIES

Pursuant to Federal Rule of Criminal Procedure 16, the government has disclosed summaries of the expert testimony of several medical professionals from whom it intends to elicit expert opinions regarding Theranos' tests. For four of the government's witnesses—Drs. Steven Linnerson, Audra Zachman, Edward Szmuc, and John Couvaras—the government intends to elicit opinions on hCG (pregnancy) tests. For the other witnesses—JoEllen Embry, Dr. Gerald Asin, and Dr. Curtis Page—the government intends to elicit testimony about various Theranos tests.¹ Each apparently had patients who received Theranos tests during the period of the charged conspiracy.

The government seeks to elicit testimony from these medical professionals about blood tests in general, specific patient tests, and the accuracy of Theranos test results, all with the imprimatur of medical expertise. But the government's expert disclosure fails to meet the most basic requirements of Rule 16(a)(1)(G). Under Rule 16, the government must summarize the proffered opinion and identify the bases of and reasons for those opinions. The government's summaries violate these requirements in two respects. First, for two experts, the government's summaries disclose topics of expert testimony without summarizing the content of the testimony. Second, for almost all the experts, the government has not disclosed the bases of and reasons for certain opinions, leaving Ms. Holmes to guess what the foundation is for those opinions. Because the government's disclosure fails to meet these requirements, the Court should exclude this testimony or, at a minimum, compel adequate summaries.

ARGUMENT

Rule 16 governs the government's disclosure obligations. Rule 16(a)(1)(G) requires the government to provide "a written summary of any testimony that the government intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence during its case-in-chief at trial." "The summary provided . . . must describe the witness's opinions, the bases and reasons for those opinions, and the

¹ The government also noticed an additional expert, Dr. Govind Acharya. Declaration of Amy Mason Saharia ("Saharia Decl."), Ex. A at 4. However, the government did not include Dr. Acharya on the witness list it served on Friday, June 26. Ms. Holmes therefore is not moving to exclude his testimony at this time.

witness's qualifications." Fed. R. Crim. P. 16(a)(1)(G). This requirement "is intended to minimize surprise that often results from unexpected expert testimony, [to] reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert's testimony through focused cross-examination." Fed. R. Crim. P. 16 advisory committee's note to 1993 amendment.

The summary of the "bases and reasons must be sufficient to allow counsel to frame a *Daubert* motion (or other motion *in limine*), to prepare for cross-examination, and to allow a possible counter-expert to meet the purport of the case-in-chief testimony." *United States v. Cerna*, 2010 WL 2347406, at *1 (N.D. Cal. June 8, 2010). "The summary of bases relied upon by the expert should cover not only written and oral reports, *tests*, reports and investigations, but *any information* that might be recognized as a legitimate basis for an opinion under Federal Rule of Evidence 703" *Id.* (emphases added) (internal quotation marks omitted). Where a witness is "so generic and routine that the testimony will be largely predictable, a shorthand summary of the witness's qualifications and testimony may be adequate." *Id.* (internal quotation marks omitted); *see also United States v. Caputo*, 382 F. Supp. 2d 1045, 1049 (N.D. Ill. 2005) ("The level of detail of this summary depends on the complexity of the expert testimony."). But in all cases, "Rule 16 requires that the government summarize each specific opinion to be offered along with the basis for it." *United States v. Cervantes*, 2015 WL 7734281, at *2 (N.D. Cal. Dec. 1, 2015).

The government's scant summaries—which involve complex medical opinions and not "generic" expert testimony—flunk this standard. After the government served its summaries on March 6, the defense three times requested that the government disclose the witnesses' opinions and the bases and reasons for their opinions. *See Saharia Decl., Ex. B.* (3.12.2020 Letter from K. Trefz to government); *Saharia Decl., Ex. C.* (4.8.2020 E-mail from K. Trefz to government); *Saharia Decl., Ex. D.* (5.6.2020 Letter from K. Trefz to government). The government ignored the first two requests. Two months following the first request, the government finally responded on May 14 that its disclosures "are more than sufficient" and refused to provide any additional information. *Saharia Decl., Ex. E.* (5.14.2020 E-mail from R. Leach to defense counsel).

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The government's summaries have two glaring deficiencies: (1) for two of its witnesses, Dr. Asin and Dr. Page, the government has not even summarized the content of their testimony; and (2) for certain opinions of almost all its witnesses, it has not disclosed the bases of and reasons for those witnesses' opinions.

I. The Government Fails To Describe Dr. Asin's and Dr. Page's Testimony.

First, with respect to Dr. Asin and Dr. Page, the government's disclosure identifies certain potential *topics* of testimony but does not actually summarize the testimony. In particular:

- The government's summary for Dr. Asin states that he will testify about "PSA tests, diabetic tests, protein and calcium tests, and HIV tests," but fails to preview his testimony (or opinion) regarding diabetic, protein, and calcium tests. The summary is completely silent as to what he will say about these tests. For the PSA test, the summary explains that, hypothetically, a doctor may need to order a painful procedure if the test results are high, but it does not explain whether he has an opinion about any Theranos PSA test, let alone what that opinion is. Saharia Decl., Ex. A at 4.
- The summary for Dr. Page states that he will testify about A1C and CBC tests, but does not identify the content of any testimony regarding the CBC test, much less the bases and reasons for any opinion about that test. *Id.* at 6. As with Dr. Asin, the government's summary is completely silent with respect to what Dr. Page will say about CBC tests.

Courts in this District have strictly enforced the requirements of Rule 16. *See Cerna*, 2010 WL 2347406, at *4; *see also United States v. Yagi*, 2013 WL 10570994, at *15-16 (N.D. Cal. Oct. 17, 2013). In *Cerna*, for example, the district court found that a summary that stated that an expert would "testify regarding MS-13 tattoos, symbols, codes, colors and graffiti, and how they are used to communicate" violated Rule 16 because it failed to identify the expert's *opinions* regarding those topics. *Cerna*, 2010 WL 2347406, at *4. Similarly, the court found that a disclosure that an expert would testify that she participated in the examination of a stolen car, and helped collect gunshot residue and forensic evidence

1 from the vehicle, violated Rule 16 because the summary failed to “specify what opinions [the expert]
2 will offer, much less the evidence taken from the [car] about which she will be testifying.” *Id.*

3 The same is true here. The government disclosed that Dr. Asin will testify about diabetic,
4 protein, and calcium tests, Saharia Decl., Ex. A. at 4, but failed to “provide[] any indication of [Dr.
5 Asin’s] actual opinions regarding those subjects, much less any bases and reasons.” *Cerna*, 2010 WL
6 2347406, at *4. The disclosure does not even state *which* diabetic tests or protein tests will be the
7 subject of his expert testimony. The government takes the same approach with Dr. Page, referencing
8 CBC tests in its summary without disclosing any opinion or testimony as to those tests. Saharia Decl.,
9 Ex. A. at 6. These summaries provide “no clue as to what [the witnesses’] opinions would be regarding”
10 those Theranos tests. *See Cerna*, 2010 WL 2347406, at *4. They do not identify, for example, whether
11 the doctors will provide opinions regarding the nature of those tests, error rates, or specific Theranos test
12 results—much less the bases of any such opinions. And the government’s interview memos for these
13 witnesses do not shed further light on what these opinions might be or their bases: Dr. Page’s indicates
14 that he ordered CBC tests from Theranos but had no issues with any test other than HbA1C; Dr. Asin’s
15 suggests that he suspected some issues with undefined diabetic, protein, and calcium tests, but the
16 summary notably excludes those potential opinions while at the same time reasserting his PSA- and
17 HIV-related opinions identified in his interview. Saharia Decl., Ex. F. at 2 (Page 302); Saharia Decl.,
18 Ex. G at 1-2 (Asin 302).

19 Complying with Rule 16 should not be difficult. The government must disclose what these
20 experts’ opinions are regarding Theranos’ tests and identify the specific reasons for and bases of these
21 experts’ opinions—including the medical reasons why they believed that certain tests were inaccurate,
22 the test results on which they based that belief, and the identities of the patients at issue. It does not
23 suffice to say that these witnesses will testify about various tests, leaving the defense to guess what the
24 substance of that testimony will be. Because the government has failed to identify these witnesses’
25 opinions, its summaries for these witnesses violate Rule 16.

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II. The Government Fails To Identify the Bases and Reasons for Certain Opinions by Dr. Asin, Dr. Page, Dr. Zachman, Ms. Embry, Dr. Linnerson, and Dr. Szmuc.

Second, for six of the witnesses, the government has not disclosed the bases and reasons for several of their opinions:

- Dr. Asin’s summary discloses that he will testify about the consequences of a high PSA test result. Saharia Decl., Ex. A. at 4. It also states that he will testify that “an HIV test result showing that it was reactive for HIV 1+2 antibodies, but non-reactive for HIV 1 antibody and HIV 2 antibody, separately, did not make any sense.” *Id.* To the extent these abstract opinions are based on actual Theranos test results, the summary does not identify the test results or patients.
- The government has disclosed that Dr. Page will testify that “he experienced a high quantity of abnormal A1C tests with Theranos testing” and “he did not understand how Theranos could not have known they had a problem with A1Cs for a couple of months.” *Id.* at 6. But the summary does not include the basis of or reason for these opinions; for example, it does not identify the results of the supposedly abnormal tests, describe what was abnormal about them, or identify the at-issue patients. As a result, Ms. Holmes cannot prepare to cross-examine Dr. Page on this issue.
- The summary for Dr. Zachman states that she will testify that she “has never had any other problems with hCG tests aside from the experience she had with her patient who was tested by Theranos.” *Id.* at 2. The summary provides no bases of or reasons for this testimony.
- The summary for Ms. Embry states that she will testify that “in 20-plus years of using Sonora Quest and LabCorp, she has never experienced any clinical errors with their lab results.” *Id.* at 3. The summary provides no bases of or reasons for that contention. Similarly, the summary states that Ms. Embry will testify that “to this day she has never had any patients with testosterone as low as what Theranos was reporting.” *Id.* The summary, however, does not identify any specific patients or the actual test results about which she intends to testify.

Without such information, the defense cannot prepare to cross-examine Ms. Embry.

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- 1 • The government’s summary for Dr. Linnerson explains he will testify that “[h]is practice has

2 never had problems with its hCG tests with other established laboratories before it started

3 using Theranos.” *Id.* at 2. The summary provides no bases of or reasons for that opinion.

4 The summary also states that “if a Theranos test showed a low value of hCG followed by a

5 test from another laboratory a few days later with a very high value, this would tend to show

6 that the Theranos test was wrong absent some other explanation,” *id.*, suggesting that Dr.

7 Linnerson intends to testify about specific Theranos tests and patients. But the summary does

8 not indicate whether he will opine about any specific patients and fails to identify any

9 specific patients or Theranos tests that form the bases of his opinions—again prejudicing Ms.

10 Holmes’ ability to prepare to meet his potential testimony at trial.
- 11 • The summary for Dr. Szmuc states that he will testify that in 30 years of using Sonora Quest,

12 he never questioned its results. Saharia Decl., Ex. A. at 3. To the extent this is an opinion

13 about whether Sonora Quest tests were inaccurate with respect to hCG, no basis of or reasons

14 for that opinion have been disclosed. The summary for Dr. Szmuc also discloses Dr.

15 Szmuc’s opinions about hypothetical tests. *See, e.g., id.* (“[I]f you have an hCG of 5,000 and

16 later one at 100,000, a next result below 5,000 indicates a problem with the test . . .”). If

17 this is intended to refer to actual Theranos tests of Dr. Szmuc’s patients, the summary does

18 not identify which tests or which patients.

19 Courts routinely exclude expert testimony when the government fails to disclose the bases and

20 reasons for the expert’s opinion. In *United States v. Valdez*, for example, the court excluded the

21 testimony of the government’s forensic expert regarding DNA testing of a bottle found in a stolen

22 government vehicle because the government’s summary of that expert testimony was deficient. 2019

23 WL 539074, at *2 (N.D. Cal. Feb. 11, 2019). The summary stated that the expert would (1) opine that

24 the DNA profiles on the bottle and the defendant were the same; (2) “explain the testing methods” used

25 to extract DNA from the stolen vehicle and the defendant; (3) explain the methods used to compare the

26 DNA samples; and (4) testify about the methods used for statistical analysis of DNA evidence in general

1 and as applied to the case. *Id.* The Court excluded the testimony, labeling the descriptions in the
 2 summary “mere generalities,” because the summary did not explain what the expert’s methods actually
 3 were. *Id.* Therefore, the Court held, the government’s “barebones disclosures” fell well short of the
 4 standards in Rule 16. *Id.*

5 The government’s summaries here provide even less detail. For example, the witnesses
 6 purportedly will opine that they have never had issues with other laboratories. Although the disclosures
 7 do not define what the witnesses mean by “problems,” presumably the government intends to use this
 8 testimony to suggest that other laboratories’ test results were accurate while Theranos’ were not. The
 9 summaries do not identify what methodologies the experts applied to arrive at those opinions, or how
 10 they came to those conclusions. If those conclusions are based purely on their failure to question other
 11 results, such opinions would be appropriately subject to a *Daubert* challenge. If they are based on
 12 research, a study, or a review of the expert’s patient records, Ms. Holmes is entitled to notice of that fact
 13 so that she can properly prepare to address the expert’s opinion either by motion or by cross-
 14 examination. Likewise, the government does not identify the test results on which the medical
 15 professionals are basing their conclusions about Theranos’ tests, rendering Ms. Holmes unable to probe
 16 the accuracy of their assertions or, potentially, to take discovery regarding other possible reasons for the
 17 test results. The current disclosures are “insufficient to allow counsel to frame a *Daubert* motion or
 18 other *motion in limine*, to prepare for cross-examination, or to allow a possible counter-expert to meet
 19 the purport of the case-in-chief testimony.” *Cerna*, 2010 WL 2347406, at *4; *see also id.* at *8 n.8 (“it
 20 is important to know the foundation for each specific opinion provided by an expert.”).

21 The Court should exclude the evidence, or in the alternative compel disclosure. Fed. R. Crim. P.
 22 16(d)(2). The disclosure by the government must allow, among other things, the defense adequately to
 23 “frame a *Daubert* motion [for these witnesses and] to prepare for cross-examination.” *Cerna*, 2010 WL
 24 2347406, at *4. Accordingly, if the Court decides that an order compelling disclosure is warranted, the
 25 disclosure should at a minimum provide: (1) an explicit opinion for each Theranos test referenced in
 26 each witness’s summary; (2) the specific patients and test results on which the witnesses are basing their
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opinions; (3) bases of and reasons for their conclusions that such test results were inaccurate or unreliable; and (4) the bases of and reasons for their opinions regarding the accuracy of other laboratories' tests. *See id* (providing explicit instructions to the government regarding the content of the summaries ordered by the Court).

CONCLUSION

The Court should exclude the at-issue testimony of these experts, or else compel the government to supplement its disclosures by August 11, 2020. *See* Fed. R. Crim. P. 16(d)(2).

DATED: July 2, 2020

Respectfully submitted,

/s/ Amy Mason Saharia

KEVIN DOWNEY

LANCE WADE

AMY MASON SAHARIA

KATHERINE TREFZ

Attorneys for Elizabeth Holmes

CERTIFICATE OF SERVICE

I hereby certify that on July 2, 2020, a copy of this filing was delivered via ECF on all counsel of record.

/s/ Amy Mason Saharia
AMY MASON SAHARIA
Attorney for Elizabeth Holmes

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Attorneys for Defendant ELIZABETH A. HOLMES

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	Case No. CR-18-00258-EJD
)	
Plaintiff,)	DECLARATION OF AMY MASON SAHARIA
)	IN SUPPORT OF MS. HOLMES' MOTION TO
v.)	EXCLUDE EXPERT TESTIMONY, OR IN THE
)	ALTERNATIVE, COMPEL ADEQUATE RULE
ELIZABETH HOLMES and)	16 DISCLOSURE
RAMESH "SUNNY" BALWANI,)	
)	
Defendants.)	Hon. Edward J. Davila
)	
)	

I, AMY MASON SAHARIA, declare as follows:

1. I represent Defendant Elizabeth Holmes and have been admitted to practice *pro hac vice* in the above-captioned matter. I submit this declaration in support of Ms. Holmes' Motion To Exclude Expert Testimony Pursuant to Rule 16. I attest to the following facts upon which the motion relies.

2. Attached to the Motion are seven exhibits. Three exhibits have been filed as attachments

1 to Ms. Holmes' Administrative Motion For Leave to File Exhibits Under Seal ("Administrative
2 Motion") because they contain confidential information. The contents of each are as follows:

3 a. Exhibit A is a true and correct copy of a March 6, 2020 letter from the
4 government providing the government's Rule 16 disclosure re: expert testimony, redacted to conceal
5 patient names pursuant to the protective order entered in this case. Redacted and unredacted copies have
6 been tendered as attachments to Ms. Holmes' Administrative Motion filed this day.

7 b. Exhibit B is a true and correct copy of a March 12, 2020 letter from Katherine
8 Trefz to the government regarding the government's Rule 16 disclosure.

9 c. Exhibit C is a true and correct copy of an April 8, 2020 email from Katherine
10 Trefz to Robert Leach regarding the government's Rule 16 disclosure.

11 d. Exhibit D is a true and correct copy of a May 6, 2020 letter from Katherine Trefz
12 to the government regarding the government's Rule 16 disclosure.

13 e. Exhibit E is a true and correct copy of a May 14, 2020 e-mail from Robert Leach
14 to defense counsel regarding the government's Rule 16 disclosure.

15 f. Exhibit F is a true and correct copy of the government's FD-302 for Dr. Curtis
16 Page bates-stamped US-REPORTS-0015101, redacted to conceal Dr. Page's personal identifying
17 information pursuant to the protective order entered in this case. Redacted and unredacted copies have
18 been tendered as attachments to Ms. Holmes' Administrative Motion filed this day.

19 g. Exhibit G is a true and correct copy of the government's FD-302 for Dr. Gerald
20 Asin bates-stamped US-REPORTS-0015043, redacted to conceal Dr. Asin's personal identifying
21 information and to conceal patient names pursuant to the protective order entered in this case. Redacted
22 and unredacted copies have been tendered as attachments to Ms. Holmes' Administrative Motion filed
23 this day.

24 I declare under penalty of perjury under the laws of the United States that the foregoing is true
25 and correct to the best of my knowledge.

1 Executed this 2nd day of July, 2020 in Southampton, NY.

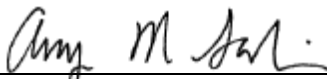
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3 
4 AMY MASON SAHARIA
5 Attorney for Elizabeth Holmes
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Exhibit B

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March 12, 2020

Via Email

Ms. Vanessa Baehr-Jones, Esquire
Mr. John C. Bostic, Esquire
Mr. Robert Leach, Esquire
Mr. Jeffrey Schenk, Esquire
Assistant United States Attorneys
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Re: United States v. Elizabeth Holmes and Ramesh "Sunny" Balwani
No. CR-18-00258-EJD (N.D. Cal.)

Dear Counsel:

We write regarding the government's March 6, 2020 letter regarding Rule 16(a)(1)(G) disclosures. The disclosures are plainly deficient, particularly as to percipient witnesses whose testimony may also cover topics and/or opinions that fall within Federal Rule of Evidence 702 and for whom no further witness memoranda or notes have been produced. Please supplement the disclosure by March 16, 2020.

1. The documents identified by Dr. Master in Appendix B of Dr. Master's report include several documents that are not identified by produced Bates number. Please provide copies of those documents.
2. Additionally, pursuant to Rule 16, *Brady*, *Giglio*, and the Jencks Act, please provide the following with respect to Dr. Master:
 - a. All communications of Dr. Master with respect to Theranos, including but not limited to:
 - i. Communications between Dr. Master and members of the media, including but not limited to John Carreyrou, producers and journalists of the *The Dropout* podcast, Abigail Tracy of *Vanity Fair*, and Nick Stockton of *Wired*;

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Vanessa Baehr-Jones, Esq., *et al.*
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- ii. Communications between Dr. Master and others regarding the August 2016 AACC presentation and panel with Ms. Holmes (including communications that occurred both before and after that event);
 - iii. Communications between Dr. Master and others regarding Theranos' submissions to *Clinical Chemistry*; and
 - iv. Communications between Dr. Master and competitors of Theranos, including but not limited to Sonora Quest and LabCorp.
 - b. Any contracts between Dr. Master and competitors of Theranos, including but not limited to Sonora Quest and LabCorp.
 - c. Any payments by competitors of Theranos, including but not limited to Sonora Quest and LabCorp, to Dr. Master.
3. Please produce, or identify in the government's productions, memoranda or notes of any government interviews or meetings with the following individuals identified in the government's disclosure as percipient witness who may provide expert testimony:
- a. Govind Acharya
 - b. Gerald Asin
 - c. JoEllen B. Embry
 - d. Curtis Page
 - e. Edward Szmuc

Although the government made a production as recently as March 4, two days before the government's disclosure was served, the defense has not yet received memoranda of interview or similar documents for any of these individuals. The government's disclosure indicates that the government has spoken to these witnesses, however. By email on Monday, March 9, I requested these materials. As of this letter, the defense still has yet to receive any such materials. As of the date of this letter, the government is five days over its disclosure deadline.

4. With respect to the disclosures for Dr. Linnerson:
- a. Please define "problem" and disclose the basis for Dr. Linnerson's opinion that his practice has "never had a problem" with Sonora Quest and LabCorp.
5. With respect to the disclosures for Dr. Zachman:
- a. Please disclose the basis for Dr. Zachman's opinion that she "has never had any other problems with hCG tests."
6. With respect to the disclosures regarding Ms. Embry:
- a. Please disclose the patients referenced in Ms. Embry's disclosure.
 - b. Please disclose the basis for Ms. Embry's opinion that she never experienced any clinical errors with the lab results of Sonora Quest and LabCorp.

WILLIAMS & CONNOLLY LLP

Vanessa Baehr-Jones, Esq., *et al.*

March 12, 2020

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- c. Please confirm that Ms. Embry will testify regarding a syndrome known as Poly Cystic Ovarian Syndrome, and not a syndrome known as Poly Cystic Ovarions Syndrome, as noted in your disclosure.
7. With respect to the disclosures regarding Dr. Szmuc:
 - a. Please disclose whether Dr. Szmuc will opine that an expected hCG value would be between 2-1,000 at any particular time and, if so, what time period.
 - b. Please explain Dr. Szmuc's opinion as to the nature and type of "red flags" that would be indicated by the last two sentences on page 3. For example, will Dr. Szmuc opine that the conditions listed indicate a red flag with respect to the pregnancy or the accuracy of the test?
 - c. Please confirm that, on page 3 of the disclosure, the phrase "In Dr. Szmuc's option" should read "In Dr. Szmuc's opinion."
8. With respect to the disclosures regarding Dr. Asin:
 - a. Please disclose definitions for "diabetic tests" and "protein" tests.
 - b. The disclosure lists several types of tests as the subject of potential testimony but only provides opinions as to PSA and HIV. Please disclose any opinions Dr. Asin may provide with respect to "diabetic tests" and "protein and calcium tests."
9. With respect to the disclosures regarding Dr. Acharya:
 - a. The disclosure indicates that Dr. Acharya "will testify about blood metabolic panel (BMP) tests, and, among other things, the electrolyte analysis and potassium analysis in these tests." Please disclose what "other things" Dr. Acharya may testify to regarding these tests.
 - b. Please define and disclose the basis for Dr. Acharya's opinion that "a BMP test is not complicated."
 - c. Please disclose the patients referenced in Dr. Acharya's disclosure, and the basis for his opinion that the test result was not right.
10. With respect to the disclosures regarding Dr. Page:
 - a. The disclosure indicates that Dr. Page will testify regarding CBC tests but does not identify any opinions regarding CBC tests. Please disclose any opinions to which Dr. Page will testify regarding CBC.
 - b. Please disclose the basis for Dr. Page's opinion that he experienced a "high quantity of abnormal A1C tests," including his opinion that it was a "high quantity" and his opinion that the tests were "abnormal."
 - c. Please disclose the basis for Dr. Page's opinion that Theranos "had a problem with A1Cs for a couple of months."

WILLIAMS & CONNOLLY LLP

Vanessa Baehr-Jones, Esq., *et al.*

March 12, 2020

Page 4

11. We note that only Dr. Zachman and Dr. Couvaras identified specific patients about whom they may provide testimony, and two others reference unnamed patients. If the other doctor witnesses will provide expert testimony regarding specific patients, please disclose that testimony, including an identification of the patients.
12. None of the disclosures provided in items 2 through 9 in the government's letter identify specific documents that would provide the "bases and reasons for [the] opinions" listed. Please disclose any documents that provide the "bases and reasons for [the] opinions" identified.

Sincerely,



Katie Treitz

cc: Jeff Coopersmith, Esq. (by email)

Exhibit C

From: Trefz, Katherine
Sent: Wednesday, April 8, 2020 8:53 PM
To: 'Leach, Robert (USACAN)'; Wade, Lance; 'Coopersmith, Jeffrey'
Cc: Downey, Kevin; Saharia, Amy; 'Cazares, Stephen'; 'Brown, Walter F. (wbrown@orrick.com)'; 'Luskey, Randy'; 'Schenk, Jeffrey (USACAN)'; 'Bostic, John (USACAN)'; 'Baehr-Jones, Vanessa (USACAN)'; 'Nedrow, Jeff (USACAN)'; 'John Cline'
Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Counsel,

Please let us know when we can expect a response to this letter.

Thanks,
Katie

Katie Trefz
Williams & Connolly LLP
725 Twelfth St., NW Washington, DC 20005
(P) 202-434-5038 | (C) 949-285-0410
ktrefz@wc.com | www.wc.com/ktrefz

From: Trefz, Katherine
Sent: Thursday, March 12, 2020 3:52 PM
To: 'Leach, Robert (USACAN)' <Robert.Leach@usdoj.gov>; Wade, Lance <LWade@wc.com>; 'Coopersmith, Jeffrey' <jcoopersmith@orrick.com>
Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; 'Brown, Walter F. (wbrown@orrick.com)' <wbrown@orrick.com>; 'Luskey, Randy' <rluskey@orrick.com>; 'Schenk, Jeffrey (USACAN)' <Jeffrey.B.Schenk@usdoj.gov>; 'Bostic, John (USACAN)' <John.Bostic@usdoj.gov>; 'Baehr-Jones, Vanessa (USACAN)' <Vanessa.Baehr-Jones@usdoj.gov>; 'Nedrow, Jeff (USACAN)' <Jeff.Nedrow@usdoj.gov>; 'John Cline' <ccline@johndclinelaw.com>
Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Counsel,

Please see the attached.

Katie

Katie Trefz
Williams & Connolly LLP
725 Twelfth St., NW Washington, DC 20005
(P) 202-434-5038 | (F) 202-434-5029
ktrefz@wc.com | www.wc.com/ktrefz

From: Trefz, Katherine
Sent: Monday, March 09, 2020 5:42 PM
To: Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>; Wade, Lance <LWade@wc.com>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>

Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; Brown, Walter F. (<wbrown@orrick.com>) <wbrown@orrick.com>; Luskey, Randy <rluskey@orrick.com>; Schenk, Jeffrey (USACAN) <Jeffrey.B.Schenk@usdoj.gov>; Bostic, John (USACAN) <John.Bostic@usdoj.gov>; Baehr-Jones, Vanessa (USACAN) <Vanessa.Baehr-Jones@usdoj.gov>; Nedrow, Jeff (USACAN) <Jeff.Nedrow@usdoj.gov>; John Cline <cline@johndclinelaw.com>
Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Bob,

Please produce (or identify in the government's productions) notes or memoranda of any government interviews or meetings with, or testimony of, the following individuals identified in the government's letter:

JoEllen B. Embry
Dr. Edward Szmuc
Dr. Gerald S. Asin
Dr. Govind Acharya
Dr. Curtis Page

Thank you,
Katie

Katie Trefz
Williams & Connolly LLP
725 Twelfth St., NW Washington, DC 20005
(P) 202-434-5038 | (F) 202-434-5029
ktrefz@wc.com | www.wc.com/ktrefz

From: Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>
Sent: Friday, March 06, 2020 11:49 PM
To: Wade, Lance <LWade@wc.com>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>
Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; Trefz, Katherine <KTrefz@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; Brown, Walter F. (<wbrown@orrick.com>) <wbrown@orrick.com>; Luskey, Randy <rluskey@orrick.com>; Schenk, Jeffrey (USACAN) <Jeffrey.B.Schenk@usdoj.gov>; Bostic, John (USACAN) <John.Bostic@usdoj.gov>; Baehr-Jones, Vanessa (USACAN) <Vanessa.Baehr-Jones@usdoj.gov>; Nedrow, Jeff (USACAN) <Jeff.Nedrow@usdoj.gov>
Subject: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Dear Counsel,

Please see the attached.

Best regards,
Bob

Robert S. Leach
Assistant United States Attorney
United States Attorney's Office
Northern District of California
1301 Clay Street, Suite 340S
Oakland, California 94612

(510) 637-3918 -- Office

(415) 793-2945 – Cell

Exhibit D

LAW OFFICES
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FAX (202) 434-5029

KATHERINE TREFZ

(202) 434-5038

ktrefz@wc.com

EDWARD BENNETT WILLIAMS (1920-1988)
PAUL R. CONNOLLY (1922-1978)

May 6, 2020

Via Email

Ms. Vanessa Baehr-Jones, Esquire
Mr. John C. Bostic, Esquire
Mr. Robert Leach, Esquire
Mr. Jeffrey Schenk, Esquire
Assistant United States Attorneys
United States Attorney's Office
Northern District of California
150 Almaden Blvd. Suite 900
San Jose, CA 95113

Re: United States v. Elizabeth Holmes and Ramesh "Sunny" Balwani
No. CR-18-00258-EJD (N.D. Cal.)

Dear Counsel:

We write to follow up on our March 12, 2020, letter regarding the government's March 6, 2020 Rule 16(a)(1)(G) disclosures. As we stated in the March 12 letter, the disclosures are plainly deficient, particularly as to percipient witnesses whose testimony may also cover topics and/or opinions that fall within Federal Rule of Evidence 702. Please supplement the disclosure as promptly as possible.

We reiterate the requests that remain outstanding from our March 12 letter and, based on the subsequent disclosure of additional memoranda and material, make additional requests.

1. Pursuant to Rule 16, *Brady*, *Giglio*, and the Jencks Act, please provide the following with respect to Dr. Master:
 - a. All communications of Dr. Master with respect to Theranos, including but not limited to:
 - i. Communications between Dr. Master and members of the media, including but not limited to John Carreyrou, producers and journalists of the *The Dropout* podcast, Abigail Tracy of *Vanity Fair*, and Nick Stockton of *Wired*;

WILLIAMS & CONNOLLY LLP

Vanessa Baehr-Jones, Esq., *et al.*
May 6, 2020
Page 2

- ii. Communications between Dr. Master and others regarding the August 2016 AACC presentation and panel with Ms. Holmes (including communications that occurred both before and after that event);
 - iii. Communications between Dr. Master and others regarding Theranos' submissions to *Clinical Chemistry*; and
 - iv. Communications between Dr. Master and competitors of Theranos, including but not limited to Sonora Quest and LabCorp.
 - b. Any contracts between Dr. Master and competitors of Theranos, including but not limited to Sonora Quest and LabCorp.
 - c. Any payments by competitors of Theranos, including but not limited to Sonora Quest and LabCorp, to Dr. Master.
2. With respect to the disclosures for Dr. Linnerson:
 - a. Please define "problem" and disclose the basis for Dr. Linnerson's opinion that his practice has "never had a problem" with Sonora Quest and LabCorp.
3. With respect to the disclosures for Dr. Zachman:
 - a. Please define "problems" and disclose the basis for Dr. Zachman's opinion that she "has never had any other problems with hCG tests."
4. With respect to the disclosures regarding Ms. Embry, and based on the subsequent disclosure of Ms. Embry's Memorandum of Interview:
 - a. Please disclose the patients referenced in Ms. Embry's disclosure.
 - b. Please disclose the basis for Ms. Embry's opinion that she never experienced any clinical errors with the lab results of Sonora Quest and LabCorp.
 - c. Please disclose the time period of the Sonora Quest errors referenced in Ms. Embry's Memorandum of Interview. *See* US-REPORTS-0014802 at 14802-14803.
5. With respect to the disclosures regarding Dr. Szmuc:
 - a. Please explain Dr. Szmuc's opinion as to the nature and type of "red flags" that would be indicated by the last two sentences on page 3. For example, will Dr. Szmuc opine that the conditions listed indicate a red flag with respect to the pregnancy or the accuracy of the test?
6. With respect to the disclosures regarding Dr. Asin:
 - a. Please disclose definitions for "diabetic tests" and "protein" tests.
 - b. The disclosure lists several types of tests as the subject of potential testimony but only provides opinions as to PSA and HIV. Please disclose any opinions Dr. Asin may provide with respect to "diabetic tests" and "protein and calcium tests."
 - c. Please disclose the basis for Dr. Asin's qualifications to opine on HIV test results.
 - d. Disclose the basis for Dr. Asin's opinion that an "HIV test result showing that it was reactive for HIV 1+2 antibodies, but non-reactive for HIV 1 antibody and HIV 2 antibody, separately, did not make any sense."

WILLIAMS & CONNOLLY LLP

Vanessa Baehr-Jones, Esq., *et al.*

May 6, 2020

Page 3

7. With respect to the disclosures regarding Dr. Acharya:
 - a. The disclosure indicates that Dr. Acharya “will testify about blood metabolic panel (BMP) tests, and, among other things, the electrolyte analysis and potassium analysis in these tests.” Please disclose what “other things” Dr. Acharya may testify to regarding these tests.
 - b. Please define and disclose the basis for Dr. Acharya’s opinion that “a BMP test is not complicated.”
 - c. Please disclose the patients referenced in Dr. Acharya’s disclosure, and the basis for his opinion that the test result was not right.
8. With respect to the disclosures regarding Dr. Page:
 - a. The disclosure indicates that Dr. Page will testify regarding CBC tests but does not identify any opinions regarding CBC tests. Please disclose any opinions to which Dr. Page will testify regarding CBC.
 - b. Please disclose the basis for Dr. Page’s opinion that he experienced a “high quantity of abnormal A1C tests,” including his opinion that it was a “high quantity” and his opinion that the tests were “abnormal.”
9. Again, we note that only Dr. Zachman and Dr. Couvaras identified specific patients about whom they may provide testimony, and two others reference unnamed patients. If the other doctor witnesses will provide expert testimony regarding specific patients, including opining as to the test results of any particular patient, please disclose that testimony, including an identification of the patients.
10. None of the disclosures provided in items 2 through 9 in the government’s letter identify specific documents that would provide the “bases and reasons for [the] opinions” listed. We have received documents for Dr. Asin. Please confirm that these are the only documents that provide the basis for his opinion. Please disclose any documents for the other fact/percipient witnesses that provide the “bases and reasons for [the] opinions” identified.

Sincerely,

A handwritten signature in black ink, appearing to read 'Katie Trefz', with a stylized, flowing script.

Katie Trefz

cc: Jeff Coopersmith, Esq. (by email)

Exhibit E

From: Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>
Sent: Thursday, May 14, 2020 4:26 PM
To: Trefz, Katherine; Wade, Lance; 'Coopersmith, Jeffrey'
Cc: Downey, Kevin; Saharia, Amy; 'Cazares, Stephen'; 'Brown, Walter F. (wbrown@orrick.com)'; 'Luskey, Randy'; Schenk, Jeffrey (USACAN); Bostic, John (USACAN); Baehr-Jones, Vanessa (USACAN); Nedrow, Jeff (USACAN); 'John Cline'
Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Dear Counsel,

We received your March 12 and May 6 letters. Our disclosures with respect to Drs. Linnerson, Zachman, Embry, Szmuc, Asin, Acharya, and Page are more than sufficient. We decline your request that we supplement our disclosures. If we interview any of them further we will produce the agent notes and any interview memorandum that is prepared.

With respect to Dr. Master, we will produce any responsive material in the government's possession. We anticipate the production will go out by May 28. We are unaware of any authority requiring the government to produce documents in the possession, custody, or control of a retained expert. If you are aware of such authority, please provide it.

Best regards,

Bob

From: Trefz, Katherine <KTrefz@wc.com>
Sent: Wednesday, May 6, 2020 11:25 AM
To: Leach, Robert (USACAN) <RLeach@usa.doj.gov>; Wade, Lance <LWade@wc.com>; 'Coopersmith, Jeffrey' <jcoopersmith@orrick.com>
Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; 'Brown, Walter F. (wbrown@orrick.com)' <wbrown@orrick.com>; 'Luskey, Randy' <rluskey@orrick.com>; Schenk, Jeffrey (USACAN) <JSchenk@usa.doj.gov>; Bostic, John (USACAN) <jbostic@usa.doj.gov>; Baehr-Jones, Vanessa (USACAN) <vbaehr-jones@usa.doj.gov>; Nedrow, Jeff (USACAN) <JNedrow@usa.doj.gov>; 'John Cline' <ccline@johndclinelaw.com>
Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

All,

Please see the attached.

Katie Trefz
Williams & Connolly LLP
725 Twelfth St., NW Washington, DC 20005
(P) 202-434-5038 | (C) 949-285-0410
ktrefz@wc.com | www.wc.com/ktrefz

From: Trefz, Katherine
Sent: Thursday, March 12, 2020 3:52 PM
To: 'Leach, Robert (USACAN)' <Robert.Leach@usdoj.gov>; Wade, Lance <LWade@wc.com>; 'Coopersmith, Jeffrey' <jcoopersmith@orrick.com>
Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; 'Brown, Walter F. (wbrown@orrick.com)' <wbrown@orrick.com>; 'Luskey, Randy'

<rluskey@orrick.com>; 'Schenk, Jeffrey (USACAN)' <Jeffrey.B.Schenk@usdoj.gov>; 'Bostic, John (USACAN)' <John.Bostic@usdoj.gov>; 'Baehr-Jones, Vanessa (USACAN)' <Vanessa.Baehr-Jones@usdoj.gov>; 'Nedrow, Jeff (USACAN)' <Jeff.Nedrow@usdoj.gov>; 'John Cline' <cline@johndclinelaw.com>
Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Counsel,

Please see the attached.

Katie

Katie Trefz

Williams & Connolly LLP

725 Twelfth St., NW Washington, DC 20005

(P) 202-434-5038 | (F) 202-434-5029

ktrefz@wc.com | www.wc.com/ktrefz

From: Trefz, Katherine

Sent: Monday, March 09, 2020 5:42 PM

To: Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>; Wade, Lance <LWade@wc.com>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>

Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; Brown, Walter F. (wbrown@orrick.com) <wbrown@orrick.com>; Luskey, Randy <rluskey@orrick.com>; Schenk, Jeffrey (USACAN) <Jeffrey.B.Schenk@usdoj.gov>; Bostic, John (USACAN) <John.Bostic@usdoj.gov>; Baehr-Jones, Vanessa (USACAN) <Vanessa.Baehr-Jones@usdoj.gov>; Nedrow, Jeff (USACAN) <Jeff.Nedrow@usdoj.gov>; John Cline <cline@johndclinelaw.com>

Subject: RE: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Bob,

Please produce (or identify in the government's productions) notes or memoranda of any government interviews or meetings with, or testimony of, the following individuals identified in the government's letter:

JoEllen B. Embry

Dr. Edward Szmuc

Dr. Gerald S. Asin

Dr. Govind Acharya

Dr. Curtis Page

Thank you,

Katie

Katie Trefz

Williams & Connolly LLP

725 Twelfth St., NW Washington, DC 20005

(P) 202-434-5038 | (F) 202-434-5029

ktrefz@wc.com | www.wc.com/ktrefz

From: Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>

Sent: Friday, March 06, 2020 11:49 PM

To: Wade, Lance <LWade@wc.com>; Coopersmith, Jeffrey <jcoopersmith@orrick.com>

Cc: Downey, Kevin <KDowney@wc.com>; Saharia, Amy <ASaharia@wc.com>; Trefz, Katherine <KTrefz@wc.com>; 'Cazares, Stephen' <scazares@orrick.com>; Brown, Walter F. (wbrown@orrick.com) <wbrown@orrick.com>; Luskey, Randy <rluskey@orrick.com>; Schenk, Jeffrey (USACAN) <Jeffrey.B.Schenk@usdoj.gov>; Bostic, John (USACAN) <John.Bostic@usdoj.gov>; Baehr-Jones, Vanessa (USACAN) <Vanessa.Baehr-Jones@usdoj.gov>; Nedrow, Jeff (USACAN) <Jeff.Nedrow@usdoj.gov>

Subject: US v. Holmes & Balwani: Rule 16(a)(1)(G) Notice

Dear Counsel,

Please see the attached.

Best regards,
Bob

Robert S. Leach
Assistant United States Attorney
United States Attorney's Office
Northern District of California
1301 Clay Street, Suite 340S
Oakland, California 94612
(510) 637-3918 -- Office
(415) 793-2945 -- Cell

This message and any attachments are intended only for the addressee and may contain information that is privileged and confidential. If you have received this message in error, please do not read, use, copy, distribute, or disclose the contents of the message and any attachments. Instead, please delete the message and any attachments and notify the sender immediately. Thank you.

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Email: cline@johndclinelaw.com

KEVIN M. DOWNEY (Admitted Pro Hac Vice)
LANCE A. WADE (Admitted Pro Hac Vice)
AMY MASON SAHARIA (Admitted Pro Hac Vice)
KATHERINE TREFZ (CA State Bar No. 262770)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
Telephone: (202) 434-5000 | Facsimile: (202) 434-5029
Email: KDowney@wc.com; LWade@wc.com; ASaharia@wc.com; KTrefz@wc.com

Attorneys for Defendant ELIZABETH A. HOLMES

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	Case No. CR-18-00258-EJD
)	
Plaintiff,)	[PROPOSED] ORDER GRANTING MS.
)	HOLMES' MOTION TO EXCLUDE EXPERT
v.)	TESTIMONY, OR IN THE ALTERNATIVE,
)	COMPEL ADEQUATE RULE 16 DISCLOSURE
ELIZABETH HOLMES and)	
RAMESH "SUNNY" BALWANI,)	
)	Hon. Edward J. Davila
Defendants.)	
)	
)	

This CAUSE having come before the Court upon Defendant Elizabeth Holmes' Motion To Exclude Expert Testimony, Or, In The Alternative, Compel Adequate Rule 16 Disclosure. After due consideration of the filings, the governing law, and the argument of the parties,

IT IS HEREBY ORDERED that Ms. Holmes' motion is GRANTED. [The proposed expert testimony of Dr. Gerald Asin regarding PSA, diabetic tests, protein tests, and calcium tests is excluded from the trial in this case; and it is

1 FURTHER ORDERED that the proposed expert testimony of Dr. Curtis Page regarding CBC
2 and A1C tests is excluded from the trial in this case; and it is

3 FURTHER ORDERED that the proposed expert testimony of Dr. Audra Zachman regarding her
4 lack of issues with hCG tests aside from the Theranos issue identified in the government's summary is
5 excluded from trial in this case; and it is

6 FURTHER ORDERED that the proposed expert testimony of Ms. JoEllen Embry regarding
7 unidentified patients' testosterone levels is excluded from trial in this case; and it is

8 FURTHER ORDERED that the proposed expert testimony of Dr. Linnerson regarding
9 unidentified Theranos test results is excluded from trial in this case; and it is

10 FURTHER ORDERED that the proposed expert testimony of Dr. Edward Szmuc regarding
11 hypothetical Theranos tests is excluded from trial in this case, and it is

12 FURTHER ORDERED that the proposed expert testimony of Ms. JoEllen Embry, Dr. Steven
13 Linnerson, and Dr. Edward Szmuc regarding the absence of issues with other laboratories is excluded
14 from the trial in this case.]

15 [The government is ORDERED to supplement its expert disclosure in accordance with Federal
16 Rule of Criminal Procedure 16(a)(1)(G). The government shall provide by August 11, 2020 a disclosure
17 that contains: (1) an explicit opinion for each Theranos test referenced in each witness's summary; (2)
18 the specific patients and test results on which the witnesses are basing their opinions; (3) bases of and
19 reasons for their conclusions that such test results were inaccurate or unreliable; and (4) the bases of and
20 reasons for their opinions regarding the accuracy of other laboratories' tests.]

21 **IT IS SO ORDERED.**

22
23 Dated _____

24 _____
25 Hon. Edward J. Davila
26 United States District Judge
27
28